REMARKS

The Office Action of November 17, 2008 presents the examination of claims 1, 3-8, 36 and 37. These claims remain pending and are not amended further.

Claims 1, 3-8, 36 and 37 stand rejected under 35 USC § 102(b) as anticipated by any one of Bijli et al. (2003), Bijli et al. (2002) or Verma et al. (200). All of these rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner is maintaining the instant rejections in error. Several errors of fact and law are expressed in the Office Action.

1. At page 3, in the paragraph at the top of the page, the Examiner states, "Claim[s] limitations such as 'hydrophobic in nature', 'resistant to trypsin', 'has no proteolytic activity', 'inhibits proteolytic cleavage of protective antigen (PA) ... would be inherent in the teachings of the prior art."

Some of the claim limitations stated are structural, *e.g.* devoid of any carbohydrate moiety". Others however, are functional, such as "inhibits proteolytic cleavage of protective antigen (PA) of *Bacillus anthracis* in a dose dependent manner" (claim 1) or "wherein the range of about 25-20 ng completely inhibits the cleavage of 5 ng of *B. anthracis* protective antigen by trypsin" (claim 5). For a functional property of a structure to be inherent it must necessarily result from the structure. It is not legally sufficient to establish inherency that the result is possible or even that it is probable. *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981); *Hansgirg v. Kemmer*, 40 USPQ 665, 667 (CCPA 1939).

In the present instance, the Examiner relies upon the description of analysis of protein fractions by SDS gel electrophoresis, and identification of the presence of proteins at 67 kDa molecular weight as disclosure of a purified 67 kDa protein that "inherently" has all the same properties as the presently claimed protein. In regard to the functional recitations in the claims, these relate to maintenance of the folded, tertiary structure of the protein, which is abolished by the SDS gel electrophoresis technique. Thus, the 67 kDa proteins described by Bijli (2003) and

Bijli (2002), even if they are indeed individual, purified proteins and have the same amino acid sequence as that of the present invention (which is not accepted by Applicants), they lack the biological activities recited in the claims.

To the degree that the Examiner might insist that, having the same amino acid sequence they would be the same proteins, Applicants note that neither of Bijli (2003) nor Bijli (2002) describe a method for purifying the 67 kDa proteins from the crude extracts described, and so these references are not enabling of purification of a protein having the biological activities recited in the present claims. Thus, neither reference is effective to establish lack of novelty of the present invention.

2. At the bottom of page 5, the Examiner begins with an assumption that the claimed protein and that described in the references are the same, "Since the protein of the prior art and the claimed invention are the same they would necessarily possess all of the same biological activities as the claimed protein." It is not clear to Applicants from where this assumption arises, but it plainly prejudices the Examiner's thinking. It may be that the Examiner believes that there is but a single protein of 67 kDa molecular weight in the grass from which the protein of the invention is isolated.

The Examiner must reconsider her thinking on this issue. One dimensional SDS gel electrophoresis is known in the art to only separate proteins on the basis of their charge to weight ratio, which is proportional to the log of their molecular weight. Thus, any "band" at a particular molecular weight is likely to include several different proteins having distinct properties, such as different isoelectric points, which can be used to further separate them, as in two-dimensional gel electrophoresis.

Attached for the Examiner's consideration is Exhibit 1, Shen et al., *Biol. Pharm. Bull.* 26:129 (2003), which shows an analysis of rice proteins by two-dimensional gel electrophoresis. The Examiner should note that, at any particular molecular weight several different proteins are seen separating along the isoelectric point dimension. (See, *e.g.* figure 2B at p. 131.)

3. At page 8, lines 3-5 of the Office Action, the Examiner states, "It should be remembered that the purification or production of a product by a particular process does not

impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner."

This is a misinterpretation of the law and furthermore misstates the facts of the present application.

With respect to the law, it is sufficient to overcome a rejection based on lack of novelty if the Applicant is able to show that the properties of the product produced by a particular process are different. It is not at all necessary that the difference be unexpected in any manner.

With respect to the facts, the Examiner's supposition that the proteins of the prior art and presently claimed are the same is unwarranted. Applicants have in the first instance provided evidence, in the form of the Arora Declaration, that the proteins are different from the protein described by Verma (2000). The protein disclosed in Verma (2000) is blocked at its amino terminus and so is not able to be sequenced by Edman degradation. In contrast, the protein of the present invention is capable of being sequenced by Edman degradation, thus having a "free" amino terminus. This represents a chemical structural distinction between the protein disclosed by Verma (2000) and the protein presently claimed.

The proteins disclosed in Bijli (2002) and Bijli (2003) are "isolated" by SDS gel electrophoresis and so are denatured and not biologically active. In contrast, the presently claimed protein has the biological activities recited in the claims, as explained above.

4. At page 8, lines 8-16, the Examiner states, "Even if applicant's [sic] product can be shown to be of higher purity than the product of the prior art reference, applicant's [sic] need to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity ... purity is relied upon." This statement is a mischaracterization of Applicants' arguments and misunderstanding of the law applicable to the present facts.

Applicants do not rely upon any assertion of increased purity of product for novelty of the claimed invention. However, even if such was Applicants' argument, in order to overcome a

rejection for lack of novelty, it is only necessary that Applicants show a distinction in structure or functionality of the product compared to the prior art. There is no need to show anything "unexpected".

In fact, Applicants have argued that the product obtained by the method of the specification is different from those disclosed by the references cited. Applicants have repeatedly emphasized that Bijli (2003) and Bijli (2002) do not even isolate a protein, they merely analyze a crude extract by SDS gel electrophoresis, but such protein as might be "isolated" as disclosed in these papers would completely lack any biological activity as it is unfolded by the conditions of the analysis. With respect to the Verma (2000) reference, the protein disclosed therein has a blocked amino terminus, and so is shown to be chemically distinct from the protein that is presently claimed, which has a "free" amino terminus. (See the Arora Declaration.)

5. Bridging pp. 8-9 of the Office Action, the Examiner states, "To address Applicant's [sic] comments regarding anthrax anti-toxin activity or ... the claimed invention must result in a structural difference between the claimed invention and the prior art to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim."

The Examiner must thus consider that the proteins of Bijli (2003) and Bijli (2002), being denatured by the SDS gel electrophoresis process used to "isolate" them, are not capable of "performing the intended use" and so do not "meet the claim."

6. At page 10, the Examiner states, "[T]he Declaration submitted by Naveen Arora merely discusses the differences in extraction and purification of the protein. The declaration concludes that since the protein of the prior art cannot be sequenced then the claimed protein and the protein of the prior art are different. As stated below, the purification or production of a product does not impart novelty or unobviousness. The declaration has failed to provide evidence that the claimed protein and the protein of the prior art are different."

This statement of the Examiner completely mischaracterizes the facts and conclusions presented in the Arora Declaration. The Examiner completely ignores paragraphs 8-10 of the

Declaration, which describe the characterization of the protein of the present invention as having a blocked amino terminus, and thus being chemically distinct from the protein described by Verma (2000). Based upon this experimental evidence, Dr. Arora concludes that the protein isolated by Verma (2000) is different from that presently claimed.

Furthermore, the Examiner is cautioned against substituting her judgment for that of the Declarant. The Examiner may not dismiss the conclusion reached by the Declarant absent some sound, scientifically reasoned explanation or evidence of her own. *In re Katzchmann* 146 USPQ 66 (CCPA 1965). Such has not been provided here.

In view of the above, Applicants respectfully submit that the present claims define allowable subject matter. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact the undersigned at the offices of Birch, Stewart, Kolasch & Birch, LLP, at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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Attachment:
Exhibit 1